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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. _____ Applicant(s) _____

09/238,741

Braslawsky et al

Examiner

Larry R. Helms Ph.D.

Group Art Unit

1642



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire NONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-46 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- ☒ Claims 1-46 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited (PTO-892)

Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____

Attachment(s) (PTO-1449)

SEE OFFICE ACTION ON THE FOLLOWING PAGES

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DETAILED ACTION

Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented the instant claims in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct antibody dimers of homodimers and heterodimers to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespectively of the improper format of the claims, because these are not proper species.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, 5-9, 14, 24-29, 37, 41, 45, and 46 in part, and claims 3, 10-13, 20, and 30-33 drawn to an antibody dimer and methods of producing an antibody dimer, classified in class 530, subclass 387.3. If Group I is elected claims 1-2, 5-9, 14, 24-29, 37, 41, 45, and 46 will be examined to the extent they read on an antibody homodimer.
 - II. Claims 1-2, 5-9, 14, 24-29, 37, 41, 45, and 46 in part, and claims 3, 10-13, 20, and 30-33 drawn to an antibody dimer and methods of producing an antibody dimer, classified in class 530, subclass 387.3. If Group II is elected claims 1-2, 5-9, 14,

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24-29, 37, 41, 45, and 46 will be examined to the extent they read on an antibody heterodimer.

- III. Claims 15 in part and claims 16 and 19, drawn to a method for treating cancer comprising contacting cancer cells with an antibody dimer, classified in class 424, subclass 133.1. If Group III is elected claim 15 will be examined to the extent the claim reads on a method with an antibody homodimer.
- IV. Claim 15, drawn to a method for treating cancer comprising contacting cancer cells with an antibody dimer, classified in class 424, subclass 136.1. If Group IV is elected the claim will be examined to the extent it reads on an antibody heterodimer.
- V. Claims 17-18, drawn to a method for treating an allergic disorder comprising administering the p5E8 homodimer to a patient, classified in class 424, subclass 133.1.
- VI. Claim 21 in part, drawn to a method of treatment, classified in class 424, subclass 133.1. If Group VI is elected claim 21 will be examined to the extent it reads on treatment with an antibody homodimer.
- VII. Claim 21 in part, drawn to a method of treatment, classified in class 424, subclass

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- VIII. Claims 22 and 23 in part, drawn to a method for treating an autoimmune disorder with an antibody dimer, classified in class 424, subclass 133.1. If Group VIII is elected the claims will be examined to the extent the dimer is a homodimer.
- IX. Claims 22 and 23, drawn to a method for treating an autoimmune disorder with an antibody dimer, classified in class 424, subclass 136.1. If Group IX is elected the claims will be examined to the extent the dimer is a heterodimer .
- X. Claims 38 and 40 in part and claim 39, drawn to a method for treating cancer with an antibody dimer, classified in class 424, subclass 133.1. If Group X is elected claims 38 and 40 will be examined to the extent they read on an antibody homodimer anti-gp 39.
- XI. Claims 38 and 40 in part, drawn to a method of treating cancer with an antibody dimer, classified in class 424, subclass 136.1. If Group XI is elected the claims will be examined to the extent the claims read on an antibody heterodimer anti-gp39.
- XII. Claim 42 in part , drawn to a method of treating cancer comprising administering the composition of an antibody dimer, classified in class 424, subclass 133.1. If Group XII is elected the claim will be examined to the extent it reads on an

the composition of an antibody dimer, classified in class 424, subclass 136.1. If

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Group XIII is elected the claim will be examined to the extent it reads on an antibody heterodimer.

XIV. Claim 43, drawn to a method for treating an autoimmune disorder comprising administering an antibody homodimer anti-CD20, classified in class 424, subclass 133.1.

XV. Claim 44 in part, drawn to a method for treating an allergic disorder comprising administering an antibody dimer, classified in class 424, subclass 133.1. If Group XV is elected the claim will be examined to the extent it reads on an antibody homodimer.

XVI. Claim 44 in part, drawn to a method of treating an allergic disorder comprising administering an antibody dimer, classified in class 424, subclass 136.1. If Group XVI is elected the claim will be examined the extent it reads on an antibody heterodimer.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II represent separate and distinct products which have different modes of operation, different functions and different effects. The antibody homodimer are specific for two antigen binding sites. The homodimer of Group I would not bind multiple

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antigens as would the heterodimer of group II. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I and II are patentably distinct.

The methods of Inventions III-XVI differ in the method objectives and method steps. Invention III recites a method of treating cancer comprising contacting cancer cells with an antibody homodimer; Invention IV recites a method for treating cancer comprising contacting cancer cells with an antibody heterodimer; Invention V recites a method for treating an allergic disorder comprising administering the p5E8 homodimer; Invention VI recites a method f treatment of an unidentified disorder with an antibody homodimer; Invention VII recites a method of treatment of an unidentified disorder with an antibody heterodimer; Invention VIII recites a method of treating an autoimmune disorder with an antibody homodimer; Invention IX recites a method for treating an autoimmune disorder with an antibody heterodimer; Invention X recites a method for treating cancer with an anti-gp39 homodimer; Invention XI recites a method for treating cancer with an anti-gp39 heterodimer; Invention XII recites a method for treating cancer in a patient with an antibody homodimer; Invention XIII recites a method for treating cancer in a patient with an antibody heterodimer; Invention XIV recites a method for treating an

Invention XVII recites a method for treating an allergic disorder in a patient with an antibody

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heterodimer. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III-XVI differ in the method objectives and method steps and are patentably distinct.

Inventions I and (III, V, VI, VIII, X, XII, XIV, and XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Group I can be used in any of the materially different methods of Groups III, V, VI, VIII, X, XII, XIV, and XV.

Inventions II and (IV, VII, IX, XI, XIII, and XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Group II can be used in any of the materially different methods of Groups IV, VII, IX, XI, XIII, and XVI.

3. Because these inventions are distinct for the reasons given above and have acquired a

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Sequence Requirements

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply

fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for

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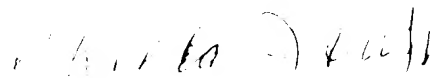
response beyond the six month statutory period. Direct the response to the undersigned.

Applicant is requested to return a copy of the attached Notice to Comply with the response.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully



(703) 306-5879

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